IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHN ALBERICI, individually and on behalf of all others similarly situated **v.** **RECRO PHARMA, INC., GERALDINE A. HENWOOD, RYAN D. LAKE, MICHAEL CELANO, STEWART MCCALLUM**, and **JOHN HARLOW**	**CIVIL ACTION** **NO. 18-2279**

MEMORANDUM RE MOTION TO DISMISS AMENDED COMPLAINT

Baylson, J. **February 14, 2020**

I. Introduction

In this securities class action, a putative class of shareholders bring claims for violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), alleging that Recro Pharma, Inc. ("Recro") and five Individual Defendants (collectively, the "Defendants") defrauded the class by failing to inform them of various concerns that had been raised to the company by industry professionals regarding the manufacturing and efficacy of Intravenous Meloxicam ("IV Meloxicam"). This drug promised to provide postoperative pain relief without many of the complications of opioids. When the company announced that the FDA declined to approve IV Meloxicam, the price of Recro's stock fell. The Amended Complaint alleges two counts:

- **Count I:** Violation of Section 10(b) of the Exchange Act and Rule 10b-5, which is asserted against all Defendants; and
- **Count II:** Violation of Section 20(a) of the Exchange Act, which is asserted against the Individual Defendants.

Defendants collectively move to dismiss the Amended Complaint under Federal Rule of Civil Procedure ("Rule") 12(b)(6) and Rule 9(b), and the Private Securities Litigation Reform Act of 1995 ("PSLRA"). The lead Plaintiff responds in opposition, and Defendants reply.

For the reasons discussed below, Defendants' Motion to Dismiss is granted without prejudice.

II. Facts[1]

A. The Parties

The lead plaintiffs are investors Daniel Wessler, Charles Clark, Ronald Davidson, and John Alberici ("Recro Investor Group" or "Plaintiff"). (ECF 21 ¶ 1.)

Defendant Recro, a "specialty pharmaceutical company" headquartered in Malvern, Pennsylvania, "develops non-opioid therapeutics for the treatment of pain in the post-operative setting." (Am. Compl. ¶¶ 2, 3.)

The Amended Complaint names five individuals who allegedly served as members of Recro's Management and Leadership teams at all relevant times:

Defendant Henwood, who founded Recro in 2007 and has served as the company's CEO, President and Director since 2008. (Am. Compl. ¶ 17.)

Defendant McCallum, who has served as Recro's Chief Medical Officer ("CMO") since December 2015. (Am. Compl. ¶ 18.)

Defendant Harlow, who has served as Recro's Executive Vice President, Commercial since 2018 and previously served as Vice President, Marketing. (Am. Compl. ¶ 19.)

[1] The following factual narrative is drawn from the Amended Complaint and disregards any differences between the Amended Complaint and the Original Complaint. See W. Run Student Hous. Assocs., LLC v. Huntington Nat'l Bank, 712 F.3d 165, 173 (3d Cir. 2013) (noting that because "the district court typically may not look outside the four corners of the amended complaint, the plaintiff cannot be bound by allegations in the superseded complaint"). The Court takes the allegations in the Amended Complaint as true and draws all reasonable inferences in favor of Plaintiff, as is required at the motion to dismiss stage. Phillips v. Cty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008).

Defendant Celano, who has served as Recro's Chief Operating Officer since January 3, 2018, and previously served as CFO. (Am. Compl. ¶ 20.)

Defendant Lake, who has served as Recro's CFO since January 2018 and previously served as Senior Vice President of Finance and Chief Accounting Officer. (Am. Compl. ¶ 21.)

B. IV Meloxicam

Recro is comprised of two segments, the Acute Care division and the Contract Development and Manufacturing Organization ("CDMO"). (Am. Compl. ¶ 24.) The Acute Care segment is "primarily focused on developing products for hospitals and other acute care settings." (Am. Compl. ¶ 25.) The product that is central to this case, IV Meloxicam, is the lead product in the Acute Care division. (Am. Compl. ¶ 31.)

IV Meloxicam is "a proprietary injectable form of meloxicam, a long-acting, non-opioid drug for the management of moderate-to-severe, acute postoperative pain." (Am. Compl. ¶ 26.) Put simply, IV Meloxicam is a non-opioid drug for post-operation management of pain. Because opioids currently dominate the market for IV acute pain, Plaintiff asserts that "Recro touts IV [M]eloxicam as having the potential to overcome many of the significant complications and side effects associated with commonly-prescribed opioid drugs, including addiction, respiratory depression, constipation, excessive nausea and vomiting." (Am. Compl. ¶ 29.) Recro conducted clinical trials of IV Meloxicam in patients recovering from both hard tissue and soft tissue procedures. (Am. Compl. ¶ 44.)

C. Feedback from the Key Opinion Leaders on IV Meloxicam

Plaintiff asserts that Recro has a "robust list"—200 to 300—of Key Opinion Leaders ("KOLs"). (Am. Compl. ¶ 38.) KOLS are "well-respected, expert physicians in their field who provide thought leadership to their peers and the general public" and assist with marketing

pharmaceuticals. (Am. Compl. ¶ 37.) Plaintiff alleges that the KOLs expressed various concerns to Recro regarding the manufacturing and efficacy of IV Meloxicam.[2] Some of the KOLs' concerns were communicated to Recro via a confidential witness, CW1, who was employed in various roles at Recro from June 2017 through May 2018 and had frequent communication with the KOLs. (Am. Compl. ¶ 39.)

The first concern expressed by the KOLs about IV Meloxicam involved the manufacturing process. IV Meloxicam is manufactured overseas pursuant to a supply agreement with an Irish company. (Am. Compl. ¶ 59.) Plaintiff alleges that "CW1 stated that approximately 30% of KOLs expressed their concern to CW1 about IV [M]eloxicam being manufactured overseas." (Am. Compl. ¶ 61.) The KOLs' concern was based on their experience with foreign manufacturing of drugs and the possibility that "a manufacturing plant in Ireland may not have the same standards as the U.S. which could cause the plant to fail the FDA pre-approval plant inspections." (Am. Compl. ¶ 62.) The KOLs also expressed concerns to CW1 about the "level and quality of oversight of the manufacturing process of IV [M]eloxicam." (Am. Compl. ¶ 63.) Plaintiff alleges that "Recro had only one employee, [Chris] Sharr, handling the oversight for manufacturing IV [M]eloxicam and its packaging in Ireland." (Am. Compl. ¶ 63.) According to Plaintiff, "CW1 and CW1's Medical Affairs Team reported the KOLs' concerns regarding … foreign manufacturing of IV [M]eloxicam to Recro's top leadership," including three of the Individual Defendants. (Am. Compl. ¶ 67.)

The second concern expressed by the KOLs regarding IV Meloxicam involved its efficacy. According to Plaintiff, "while 99.9% of KOLs were convinced that IV [M]eloxicam should be

[2] The Amended Complaint contains various allegations related to concerns raised by the KOLs about alleged nepotism at Recro. (Am. Compl. ¶¶ 32–42.) The Court will not address the nepotism allegations because, as acknowledged by Plaintiff, Recro fully "disclose[d] the family relationships" that Plaintiff alleges were suspect. (ECF 41, Plaintiff's Supplemental Submission at 5.)

used in orthopedic [hard tissue] procedures, … KOLs stated that IV [M]eloxicam should not be used in soft tissue procedures ….” (Am. Compl. ¶ 69.) Plaintiff alleges that “the clinical trial data for the efficacy of IV [M]eloxicam in hard tissue procedures … was far more compelling than the clinical trial data for the drug’s efficacy in soft tissue procedures.” (Am. Compl. ¶ 69.) This is likely because soft tissue procedures are less painful, so the reduction of pain that results from using IV Meloxicam is less pronounced when the drug is used to treat postoperative pain arising from a soft tissue procedure. (Am. Compl. ¶ 70.) Plaintiff alleges that Defendants were fully aware that “soft tissue physicians were not a receptive market for IV [M]eloxicam,” but nonetheless made statements to convey to the market that “soft tissue surgeons and their patients were ‘IV [M]eloxicam target opportunities.’” (Am. Compl. ¶ 73.)

D. Recro Files a New Drug Application for IV Meloxicam

On July 31, 2017, Recro announced that it had filed a New Drug Application (“NDA”) for IV Meloxicam 30 mg with the Food and Drug Administration (“FDA”). (Am. Compl. ¶ 46.) Recro allegedly conducted “efficacy and safety clinical trials” in preparation for filing its NDA. (Am. Compl. ¶ 43.) Plaintiff alleges that, according to the KOLs, Recro’s efficacy data was “far less robust” for the abdominoplasty (soft tissue) clinical trial than it was for the bunionectomy (hard tissue) clinical trial—a result of the difference in the extent to which the different patient classes reported a reduction in pain. (Am. Compl. ¶ 45.)

On September 28, 2017, Recro announced that the FDA had “accepted for review its NDA,” and on October 5, 2017, it announced that the FDA had set May 26, 2018 as the date by which the FDA would complete its review (the “PDUFA date”). (Am. Compl. ¶¶ 47, 48.) Plaintiff asserts that “[m]any drug companies choose to disclose their PDUFA dates in the hopes that doing so will lead to an increase in their share prices.” (Am. Compl. ¶ 49.)

E. The FDA Rejects Recro's NDA

On May 24, 2018, the FDA rejected Recro's NDA in a Complete Response Letter ("CRL"). (Am. Compl. ¶ 50.) A "CRL[] inform[s] drug companies that the review cycle for an NDA has been completed and that the NDA is not approvable. They lay out deficiencies and outline possible remedies. CRLs can have a devastating effect on a small company's share value" and are "usually confidential." (Am. Compl. ¶¶ 51, 52.)

Recro issued a press release when it received the CRL, stating that the FDA declined to approve the NDA. (Am. Compl. ¶ 53.) The press release explained that

> The CRL states that data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect does not meet the expectations of the FDA. In addition, the CRL raised CMC [or Chemistry, Manufacturing and Controls]-related questions on extractable and leachable data provided in the NDA.

(Am. Compl. ¶ 103.) Plaintiff alleges that during a morning conference call on May 24, 2018, Defendant Henwood stated that "to the best of our understanding right now, there is a lack of clarity in the reviewer's mind about some of the data." (Am. Compl. ¶ 54.) Plaintiff states that "Recro's share price was decimated as a result of the news. The stock dropped from $6.79, or 54.67%, to close at $5.63 on May 24, 2018." (Am. Compl. ¶ 55.)

According to Plaintiff, it is "very likely" that Recro knew the FDA was going to reject its NDA. (Am. Compl. ¶ 57.) This allegation is based on the fact that after the FDA accepts an NDA for review, it will "send information requests, raise further questions, have meetings, and may make recommendations to the drug company applicant." (Am. Compl. ¶ 56.) Plaintiff alleges that this practice made it likely that "Recro was aware of, but failed to disclose, the two issues raised by the FDA in deciding not to approve the NDA."[3] (Am. Compl. ¶ 57.)

[3] The Amended Complaint does not explain "the two issues raised by the FDA." This is presumably a reference to the two concerns raised by the KOLs regarding (a) potential inadequacy in manufacturing oversight and (b) the fact that IV Meloxicam was marketed as a drug to solve pain following soft-tissue procedures when the KOLs were not

III. Procedural History

Plaintiff filed his Complaint on May 31, 2018. (ECF 1.) On October 5, 2018, this Court appointed Daniel Wessler, Charles Clark, Ronald Davidson, and John Alberici (collectively "Recro Investor Group" or "Plaintiff") as the Lead Plaintiff. (ECF 21.) Plaintiff filed an Amended Complaint on December 11, 2018. (ECF 26.) Defendants moved to dismiss the Amended Complaint on February 8, 2019, (ECF 31),[4] and Plaintiff responded in opposition on April 9, 2019, (ECF 32.) Defendants replied, (ECF 33), and attached as Exhibit A summary chart of all of the misstatements alleged by Plaintiff to be misleading, together with its defense to each statement, (ECF 33-1.) The Court held oral argument on the Motion to Dismiss on June 26, 2019. (ECF 37; ECF 39, June 26, 2019 Hr'g Tr.)

Following oral argument, the Court invited the parties to submit supplemental briefing. On August 30, 2019, Plaintiff filed a supplemental memorandum in further opposition to Defendants' Motion to Dismiss. (ECF 41.) Attached to Plaintiff's supplemental memorandum as Exhibit A is a counter-chart responding to Defendants' chart. (ECF 41-1.) On September 27, 2019, Defendants filed their supplemental memorandum, (ECF 43), and attached a chart that responded to Plaintiff's counter-chart, (ECF 43-2.)

IV. Legal Standard

A securities fraud complaint must do much more than a typical complaint. In addition to the traditional Rule 12(b)(6) standard, a securities fraud complaint must satisfy Rule 9(b)'s particularity requirement. Moreover, a securities fraud complaint must comply with the

impressed by the clinical data on efficacy in the soft-tissue context. There is a difference between, on the one hand, Recro being aware that the KOLs raised these concerns prior to the FDA's rejection of the NDA and, on the other, Recro being aware that the FDA raised these concerns in its decision to deny approval. This gap in logic is addressed briefly in subsection V.E.2's analysis of loss causation.

[4] The caption of the action was amended to add two individual defendants, Stewart McCallum and John Harlow. (ECF 27, ECF 28.)

heightened pleading requirements of the PSLRA, which "imposes another layer of factual particularity to allegations of securities fraud." In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002).

A. Pleading Standard Under Rule 12(b)(6)

In considering a motion to dismiss under Rule 12(b)(6), the Court "accept[s] all factual allegations as true [and] construe[s] the complaint in the light most favorable to the plaintiff." Warren Gen. Hosp. v. Amgen Inc., 643 F.3d 77, 84 (3d Cir. 2011) (internal quotation marks and citations omitted). The Supreme Court has instructed that, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

The Court in Iqbal explained that, although a court must accept as true all of the factual allegations contained in a complaint, that requirement does not apply to legal conclusions; therefore, pleadings must include factual allegations to support the legal claims asserted. 556 U.S. at 678, 684. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 678. Accordingly, to survive a motion to dismiss, a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

B. Pleading Standard Under Rule 9(b) and the PSLRA

All allegations of fraud must meet Rule 9(b)'s "particularity" requirement. "Rule 9(b)'s heightened pleading standard gives defendants notice of the claims against them, provides an increased measure of protection for their reputations, and reduces the number of frivolous suits brought solely to extract settlements." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410,

1418 (3d Cir. 1997).

Rule 9(b) may be satisfied by describing "the circumstances of the alleged fraud with precise allegations of date, time, or place, or by using some means of injecting precision and some measure of substantiation into [the] allegations of fraud." Bd. of Trs. of Teamsters Local 863 Pension Fund v. Foodtown, Inc., 296 F.3d 164, 172 n.10 (3d Cir. 2002) (internal quotation marks and citations omitted). Stated differently, the plaintiff must plead the "who, what, when, where, and how" of the fraud. Institutional Inv'rs Grp. v. Avaya, Inc., 564 F.3d 242, 253 (3d Cir. 2009); see Bonavitacola Elec. Contractor, Inc. v. Boro Developers, Inc., No. CIV.A. 01-5508, 2003 WL 329145, at *6 (E.D. Pa. Feb. 12, 2003) (Baylson, J.) ("While a complaint need not set out 'precise words,' it should adequately describe the nature and subject of an alleged misrepresentation."). Rule 9(b)'s particularity requirement is "rigorously applied in securities fraud cases." Burlington, 114 F.3d at 1417. [B]oilerplate and conclusory allegations will not suffice." Id. at 1418.

However, "courts should be sensitive to the fact that application of [Rule 9(b)] prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud. Accordingly, the normally rigorous particularity rule has been relaxed somewhat where the factual information is peculiarly within the defendant's knowledge or control." Id. (internal quotation marks and citations omitted).

The PSLRA[5] imposes two distinct, heightened pleading requirements for actions brought under Section 10(b) and Rule 10b-5. First, the PSLRA requires that "the complaint … specify each statement alleged to have been misleading, the reason or reasons why the statement is

[5] The PSLRA was enacted "to curb perceived abuses of the § 10(b) private action—'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class action lawyers.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 320 (quoting Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 81 (2006)). The "substantive and procedural controls" imposed by the PSLRA include procedures for the appointment of lead plaintiffs and lead counsel; limitations on damages and attorney's fees; a safe harbor for forward-looking statements; sanctions for frivolous litigation; authorization for a stay of discovery pending decision on a motion to dismiss; and additional pleading requirements. Tellabs, 551 U.S. at 320.

misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint [must] state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Second, the PSLRA requires that "the complaint … state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). In a nutshell, the PSLRA requires that "securities fraud complaints 'specify' each misleading statement; … set forth the facts 'on which a belief' that a statement is misleading was 'formed'; and … 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 345 (2005) (quoting 15 U.S.C. §§ 78u-4(b)(1), (2)).

The PSLRA's pleading standard for private securities actions essentially replaced Rule 9(b)'s heightened pleading standard for claims of fraud. The particularity requirement in Rule 9(b) "is comparable to and effectively subsumed by the requirements of … the PSLRA." Avaya, 564 F.3d at 253 (internal quotation marks and citations omitted). Therefore, securities fraud plaintiffs must "plead the who, what, when, where and how" of the alleged fraud. Id. However, for allegations that are made on information and belief, "the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b); see also Avaya, 564 F.3d at 253 ("[W]hen allegations are made on information and belief, the complaint must not only state the allegations with factual particularity, but must also describe the sources of information with particularity, providing the who, what, when, where and how of the sources, as well as the who, what, when, where and how of the information those sources convey.").

V. Discussion

A. Legal Framework: Section 10(b), Rule 10b-5, and Section 20(a)

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security registered on a national securities exchange … any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe …." 15 U.S.C. § 78j(b). Rule 10b-5, which was created under Section 10(b), makes it unlawful "[t]o make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). Stating a claim under Section 10(b) and Rule 10b-5 requires the plaintiff to establish six elements:

(1) A material misrepresentation or omission by the defendant;
(2) Scienter;
(3) A connection between the misrepresentation or omission and the purchase or sale of a security;
(4) Reliance upon the misrepresentation or omission;
(5) Economic loss; and
(6) Loss causation.

Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37-38 (2011).

Section 20(a) of the Exchange Act provides that "[e]very person who, directly or indirectly, controls any person liable [for a Section 10(b) violation] shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act … constituting the violation …." 15 U.S.C. § 78t(b). Therefore, liability under Section 20(a) runs with liability under Section 10(b). Avaya, 564 F.3d at 280. If there is no liability under Section 10(b), there is no control person liability under Section 20(a). Id.

B. Statements Alleged to be False and/or Misleading

Plaintiff alleges that Recro made twenty-five false and/or misleading statements over the class period, which runs from July 17, 2017 through May 23, 2018. (Am. Compl. ¶ 1.) Plaintiff separates the allegedly false and misleading statements by the fiscal quarter in which they were made: five statements that were made during the third quarter of 2017 (July 1, 2017–September 30, 2017), (Am. Compl. ¶¶ 74–78); six statements that were made during the fourth quarter of 2017 (October 1, 2017–December 31, 2017), (Am. Compl. ¶¶ 80–85); nine statements that were made during the first quarter of 2018 (January 1, 2018–March 31, 2018), (Am. Compl. ¶¶ 87–95); and five statements that were made during the second quarter of 2018 (April 1, 2018–June 30, 2018), (Am. Compl. ¶¶ 97–101, 103.)

The Appendix to this Memorandum collects the alleged misstatements or omissions, maintaining the language emphasized by Plaintiff. The statements that Plaintiff alleges violate the Exchange Act can be grouped into five basic categories:[6]

- (1) **Investor Presentation Statements:** Statements in investor presentations suggesting that IV Meloxicam is suitable for use in soft-tissue procedures, (Am. Compl. ¶¶ 74, 77, 78, 81, 84, 85, 87, 88, 89, 90, 94, 95, 100, 101.)

- (2) **Sarbanes-Oxley Act (SOX) Certifications:** Certifications of mandatory disclosures (e.g., Form 10-Q and Form 10-K) pursuant to SOX, (Am. Compl. ¶¶ 75, 82, 91, 97.)

- (3) **Contract Manufacturer Statement:** One statement in Recro's 2017 10-K noting that Recro has "internal managers" overseeing manufacturing, (Am. Compl. ¶ 92.)

- (4) **Revenue Statements:** Statements in mandatory disclosures noting that the Acute Care segment does not bring in revenue and has costs associated with IV Meloxicam's clinical trials, (Am. Compl. ¶¶ 76, 83, 93, 98.)

[6] Although Plaintiff takes issue with two broad omissions (omissions related to the degree of oversight of foreign manufacturing and omissions related to the KOLs' concerns about the efficacy of IV Meloxicam in soft tissue procedures), the vast majority of the twenty-five misrepresentative statements deal with the latter category of omission.

- (5) **Investor Relations Statements:** Statements in press releases and on earnings calls suggesting that IV Meloxicam is suitable for use in soft tissue procedures, (Am. Compl. ¶¶ 80, 99.)

Plaintiff alleges that these statements are misleading or false because they failed to disclose "that: (i) KOLs told the Company that the clinical data for IV [M]eloxicam did not have a sufficient analgesic effect for soft tissue procedures and should not be used in soft tissue procedures; and (ii) Recro did not have a handle on the manufacturing process for IV [M]eloxicam, even though KOLs had raised concerns about Sharr's qualifications and his lack of oversight of manufacturing." (Am. Compl. ¶¶ 79, 86, 96, 102.)

C. Judicial Notice

Plaintiff and Defendants have each requested that the Court take judicial notice of certain materials.

First, Plaintiff requests that the Court take judicial notice of a March 22, 2019 press release announcing Recro's receipt of a second CRL in which the FDA declined to approve IV Meloxicam, as well as a webcast of a conference call in which Henwood stated that "[t]he FDA did focus on the … fact that some patients have a reduction in pain relief in the waning hours of the dosing period. We believe that the product does perform well, that it has a role, that it could be useful in multi-model analgesia. That's based on KOL feedback …." (ECF 32, Plaintiff's Opposition at 11.) This request need not be evaluated because Defendants do not oppose the Court taking judicial notice of the March 22, 2019 press release. (ECF 43, Defendants' Supplemental Submission at 8-9.)

Second, Defendants request that the Court take judicial notice of a press release that was issued by Recro on October 31, 2019 announcing that "it … received a written decision from the [FDA] granting its appeal of the [CRL] relating to the … [NDA] seeking approval for … IV

[M]eloxicam." (ECF 44, Ex. A.) Defendants argue that the press release is "integral" to the issues in the Amended Complaint as well as the Motion to Dismiss. (ECF 44, Request for Judicial Notice at 3.) Plaintiff responds in opposition, asserting that the FDA's decision to grant Recro's appeal fifteen months after the denial is irrelevant to whether Defendants committed securities fraud violations during the class period. (ECF 45 at 1.)

A district court evaluating a motion to dismiss under Rule 12(b)(6) may take judicial notice of (1) exhibits attached to the complaint; (2) matters of public record; and/or (3) undisputedly authentic documents integral to or explicitly relied upon in the complaint without violating the principle that "matters extraneous to the pleadings" should not be considered. Burlington, 144 F.3d at 1426; see also In re Egalet Corp. Sec. Litig., 340 F. Supp. 3d 479, 496 (E.D. Pa. 2018) (Baylson, J.) (listing exceptions). Moreover, Federal Rule of Evidence 201(b)(2) permits courts to "judicially notice a fact that is not subject to reasonable dispute because it can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." The October 31, 2019 press release was not attached to or relied on in the Amended Complaint (indeed, the press release was not published until many months after the filing of the Amended Complaint), so the first and third exceptions do not apply. Judicial notice is only proper if the press release is a public record.

Documents approved by the Third Circuit as "public records" that may be judicially noticed include "SEC filings, published reports of administrative bodies, … criminal case dispositions and decision letters of government agencies." Egalet, 340 F. Supp. 3d at 496 (internal quotation marks and citations omitted). By contrast, [a]rticles published in accounting journals and law reviews, conference call transcripts, … and company web sites … are not 'matters of public record.'" In re Astea Int'l Inc. Sec. Litig., Civil Action No. 06-1467, 2007 WL 2306586, at *8 (E.D. Pa. Aug. 9,

2007) (Yohn, J.). The key question is not accessibility, but rather whether "the public had unqualified access" to the document at issue. Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1197 (3d Cir. 1993).

The Court declines to take judicial notice of the October 31, 2019 press release regarding the FDA's grant of Recro's appeal of the CRL because this document is not within the scope of the Third Circuit's narrow construction of the "public records" exception. See Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014) (holding that press releases not attached to the complaint could "not be considered at the motion to dismiss stage" because the complaint was not "based" on the press releases); see also Toner v. GEICO Ins. Co., 262 F. Supp. 3d 200, 205 n.3 (E.D. Pa. 2017) (Slomsky, J.) (construing the public records narrowly).

D. Parties' Arguments

The Motion to Dismiss articulates six independent reasons for why the Amended Complaint should be dismissed, raising arguments under the first, second, and sixth elements. Plaintiff responds in opposition to each theory set forth by Defendants.

First, Defendants assert that Plaintiff failed to plead a materially misleading misrepresentation or omission. According to Defendants, "Plaintiff's allegations based on the opinions of KOLs … cannot form the basis of a claim against Recro because there is no legal duty for a company to disclose the opinions of third parties." (Motion to Dismiss at 2-3.) Second, Defendants argue that many of the allegedly fraudulent statements are protected by the PSLRA's safe harbor for forward looking statements, and therefore are not actionable as misleading misstatements. (Id. at 3.) Third, Defendants assert that the Amended Complaint does not meet the PSLRA's specificity requirement, in part because Recro fully disclosed the facts underlying the KOLs' alleged opinions regarding the efficacy of IV Meloxicam for soft tissue procedures.

(Id.) Fourth, Defendants contend that Plaintiff's allegations of scienter are insufficient to satisfy the "strong inference" standard because "Plaintiff makes no allegation that could form the basis of scienter, such as allegations relating to stock sales by Defendants or any motive of Defendants to act fraudulently." (Id.) Fifth, Defendants argue that Plaintiff fails to make any allegations regarding loss causation. (Id.) Sixth, Defendants explain that because Section 20(a) liability is derivative of Section 10(b) liability, and because there is no Section 10(b) liability, Count II should be dismissed. (Id.)

Further, Defendants' chart notes specific reason(s) why each of the twenty-five alleged misstatements do not satisfy the requirements of Section 10(b). Defendants contend that: the statements in paragraphs 74, 77, 78, 81, 84, 85, 87, 88, 89, 94, 100 of the Amended Complaint are forward-looking statements and the statements in paragraphs 80 and 99 are corporate puffery, so these statements are protected by the PSLRA's safe harbors; the statements in paragraphs 75, 82, 91, 97 of the Amended Complaint are disclaimers or legal conclusions; and the statements in paragraphs 76, 83, 90, 92, 93, 95, 98, 101 of the Amended Complaint do not contain an allegation of falsity (i.e., there was no misrepresentation or omission).

E. Analysis

The Court will address Defendants' arguments that (1) the opinions of the third-party KOLs were not material; (2) the Amended Complaint is devoid of scienter allegations; (3) the loss causation allegations are lacking.

Initially, the Court notes that the various statements differ in the degree to which they are misleading and/or covered by Section 10(b)—for some statements, there is no clear theory of falsity, and for others, the applicability of the PSLRA's safe harbors raise legitimate questions about actionability. This Memorandum will not engage in statement-by-statement analysis

because the insufficiency of the scienter allegations applies to all of the alleged misrepresentations. Plaintiff's failure to adequately plead scienter obviates the need to assess the statements individually, because regardless of the Court's conclusion on falsity and the PSLRA's safe harbors, the lack of scienter is fatal.

Before reaching the scienter question, however, the Court will analyze Defendants' arguments on materiality and loss causation. Like scienter, the arguments on both of these elements apply to all of the misrepresentations.

1. Materiality of Opinions of Third-Party KOLs

Defendants argue that "[t]here is no legal duty for a company to disclose the opinions of third parties. Rather, the duty to disclose is for facts and not opinions." (Motion to Dismiss at 11.) Plaintiff responds that because Recro chose to speak on the efficacy of IV Meloxicam in soft tissue procedures and the sufficiency of Recro's oversight controls, "Defendants were bound to discuss these issues in a manner that would not mislead investors as to potentially negative information within their possession." (Plaintiff's Opposition at 20.)

Defendants contend that even if the KOLs' opinions were material, Recro's public disclosure of all of its clinical data for both hard tissue and soft tissue procedures rendered the omissions not misleading. (Defendants' Supplemental Submission at 6.) Plaintiff responds that the disclosure of the clinical trial data is inadequate because "[n]o matter how many times investors review the clinical trial data, they are not able to discern from such disclosures that the Company's trusted KOLs, on whom [Recro] relied, had specifically told [Recro] that IV Meloxicam should not be used in soft tissue procedures." (Plaintiff's Supplemental Submission at 9.)

The questions of whether the KOLs' opinions were material, and relatedly, whether

disclosure of the data underlying the KOLs' opinions rendered the statements regarding the efficacy of IV Meloxicam for use in soft-tissue procedures not misleading, are foundational to this case. If the KOLs' opinions were not material, or if the disclosure of the clinical data rendered the alleged omissions related to soft tissue efficacy not misleading, then there is no liability under Section 10(b). The Court concludes that, in the context of the statements made by Recro regarding the potential for IV Meloxicam to be used in soft tissue procedures, the KOLs' statements would have been considered significant by the reasonable investor, and that the statements still could have been misleading despite Recro's disclosure of the clinical data.

a. The KOLs' Opinions Were Material In the Context of Recro's Statements

There is no requirement or general duty under the Exchange Act "to provide the public with all material information." Burlington, 114 F.3d at 1432; see also Matrixx, 563 U.S. 27, 45 (2011) ("Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose … by controlling what they say to the market."); Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17 (1988) ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). However, a duty to disclose "may arise when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure." Oran v. Stafford, 226 F.3d 275, 285-86 (3d Cir. 2000). Plaintiff does not allege that there was insider trading or required disclosure here; Plaintiff's theory is that because Recro chose to speak on IV Meloxicam's efficacy and manufacturing, it was duty-bound to do so in a way that was not misleading. Because Recro chose to make representations regarding its manufacturing process and focus on the soft tissue market, it had an obligation to ensure that those representations were not materially misleading. 17 C.F.R. § 240.10b-5(b); see also Williams v. Globus Med., Inc., 869 F.3d 235, 241 (3d Cir. 2017) ("Once a company has chosen to speak on an issue—even an issue it

had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading."); In re Urban Outfitters, Inc. Sec. Litig., 103 F. Supp. 3d 635, 652 (E.D. Pa. 2015) (Restrepo, J.) ("By specifically pointing out … areas of [the defendant's] business activities, [the] defendants put these topics 'in play' and triggered a duty to disclose and correct" prior disclosures).

The test for securities fraud materiality is whether there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Matrixx, 563 U.S. at 38 (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). "An omitted fact is material if there is a substantial likelihood that, under all the circumstances, the omitted fact would have assumed actual significance in the deliberations of the reasonable shareholder." Shapiro v. UJB Fin. Corp., 964 F.2d 272, 280 n.11 (3d Cir. 1992) (quoting TSC Industries, 426 U.S. at 449).

Matrixx, the most recent Supreme Court decision to analyze Section 10(b)'s materiality requirement, is factually similar and procedurally on point. The question in Matrixx was whether the plaintiff sufficiently alleged the materiality of adverse event reports associated with the defendant's pharmaceutical product to survive the defendant's Rule 12(b)(6) challenge. 563 U.S. at 30. Matrixx refused to endorse a bright line rule, concluding instead that "assessing the materiality of adverse event reports is a 'fact-specific' inquiry … that requires consideration of the source, content, and context of the reports." Id. at 43. Applying this standard, the Supreme Court found that the plaintiff adequately pleaded materiality because the defendant represented that the product would multiply revenues, but it had received information that plausibly connected the same product to a negative effect. Id. at 47. The negative information that the company received included the reports of three medical experts summarizing cases of ten patients who experienced

the side effect after using the product, and the fact that two professionals presented their findings of a causal link at a medical conference. Id. at 45.

Applying the rationale and holding of Matrixx indicates that materiality is sufficiently established for purposes of Defendants' Motion. Plaintiff pleaded that Recro spoke optimistically and positively about the use of IV Meloxicam for soft tissue uses—Recro spoke of intra-abdominal procedures (a soft tissue procedure) as a "target opportunity," (Am. Compl. ¶¶ 74, 77, 78, 81, 84, 85, 87, 88), and identified "GI/Colorectal" procedures (a soft tissue procedure) as a "core target." (Am. Compl. ¶¶ 81, 84, 85, 87, 88, 90, 94, 100.) Yet, according to the Amended Complaint, thirty percent of the KOLs expressed concern to Recro about the oversight of manufacturing of IV Meloxicam, and an undisclosed number of KOLs advised the company that in their view the clinical data showed that IV Meloxicam was not suited for use in soft tissue patients.

The FDA presumably used the same clinical data that the KOLs analyzed in considering Recro's NDA. Therefore, the fact that at least some of these esteemed medical professionals thought IV Meloxicam was not efficacious for soft tissue uses makes it plausible that the FDA would be concerned about efficacy as well—a fact that is highly relevant to investors, especially because IV Meloxicam is Recro's lead product. See id. at 47 (concluding materiality requirement was satisfied in large part because the defendant "had information indicating a significant risk to its leading revenue-generating product" but represented that the concerns were "completely unfounded"). Moreover, Recro did not conduct any further studies to explore the KOLs' concerns about IV Meloxicam efficacy. See id. (noting that despite evidence of a "biological link" between the product and a bad side effect, the company did not "conduct[] any studies of its own to disprove that link"). The parallels are clear and, as the Supreme Court did in Matrixx, this Court finds the allegations sufficient to establish materiality.

b. The Statements Could Be Misleading Despite Recro's Disclosure of the Clinical Data Regarding IV Meloxicam

Since materiality is concerned with the "total mix" of information available to the investor, a statement or omission cannot be materially misleading "if the allegedly undisclosed facts have … already entered the market." Anderson v. Stonemor Partners, L.P., 296 F. Supp. 3d 693, 702 (E.D. Pa. 2017) (Robreno, J.). Therefore, dismissal of a securities fraud complaint may be proper if the company adequately disclosed the information that allegedly made the statements misleading. See Winer Family Tr. v. Queen, No. Civ.A. 03-4318, 2004 WL 2203709, at *4 (E.D. Pa. Sept. 27, 2004) (Padova, J.) ("A motion to dismiss may be granted if the company's SEC filings or other documents disclose the very information necessary to make their public statements not misleading.") (internal quotation marks and citations omitted). Two precedential Third Circuit opinions illustrate this proposition.

First, in Ieradi v. Mylan Laboratories, Inc., the Third Circuit affirmed dismissal of a securities fraud complaint where the defendant company disclosed the possibility of adverse agency action but did not disclose the underlying contractual documents related to the agency's investigation. 230 F.3d 594, 596 (3d Cir. 2000). In Ieradi, the defendant was under investigation by the Federal Trade Commission ("FTC") for suspected antitrust violations related to the existence of exclusive supply contracts and disclosed this fact in various SEC filings. Id. at 597. The FTC investigation resulted in the filing of civil charges, which led to a drop in the company's stock price. Id. at 597-98. A shareholder who purchased prior to the filing of the FTC's action sued alleging that "in commenting on the FTC investigation [the company] had a duty to disclose the existence and substance of its exclusive supply contracts … so that … reasonable investors could intelligently assess the risk that the FTC investigation would result in a civil antitrust action …." Id. at 598-99. The Third Circuit affirmed the district court's conclusion that the failure to

specifically disclose the exclusive supply contracts was not material, because the company unambiguously disclosed the fact of the FTC investigation. Id. at 599. On the question of whether disclosure of the exclusive supply contracts would have given a reasonable investor the ability to evaluate the risk of an FTC enforcement action, Ieradi "seriously doubt[ed] that 'the reasonable investor' possesse[d] the depth of antitrust law expertise that would allow him or her to conclude that the contracts were susceptible to successful attack under the antitrust laws." Id. at 600.

More recently, in Fan v. StoneMor Partners LP, the Third Circuit addressed the materiality of an alleged misrepresentation in light of the company's disclosure of "facts and information that would render the alleged misrepresentations not misleading." 927 F.3d 710, 716 (3d Cir. 2019). The issue in Fan was whether certain disclosures regarding the defendant's accounting practices were sufficient to render immaterial statements touting its financial health and ability to pay down a credit facility. Id. at 715. The defendant, which provided funeral services, was required by state law to hold a certain percentage of sales proceeds in trust until the death of the customer ("pre-need sales"). Id. at 713. This requirement resulted in a disparity between the defendant's overall sales and its accessible cash, because Generally Accepted Accounting Principles ("GAAP") do not permit pre-need sales to be reported as current revenue. Id. To compensate, the defendant issued standard GAAP financials and non-GAAP financials (which included the pre-need sales in the revenue calculation); and borrowed cash to distribute the pre-need sales to investors in the same quarter in which the sale occurred, using equity sales to pay down the borrowed cash. Id. at 713-14. Fan held that the issuance of both GAAP and non-GAAP financials "render[ed] any … perceived misstatement [regarding the fact that the defendant's distributions were not funded from operating revenue] immaterial" because they "demonstrated the mathematical reality" of the defendant's accounting practices. Id. at 717.

Ieradi and Fan reveal that disclosure of information that is typical to a public filing (e.g., knowledge of possible adverse agency action in Ieradi or the accounting statements in Fan) may render a company's failure to provide further disclosures immaterial. However, Ieradi's conclusion that "[k]nowledge that the FTC was engaging in an investigation … was much more informative to the 'reasonable investor' than information pertaining to [the source of the FTC's concerns]" indicates there is a nuance to the analysis: the information that is disclosed must be accessible to the reasonable investor. Ieradi, 230 F.3d at 600.

Because of this nuance, the Court rejects Defendants' analogy to Fan. In Fan, the information that was disclosed (accounting statements) was presumably accessible to the reasonable investor who is fluent in financial metrics. By contrast, here the data that was disclosed was clinical data for the pain relief provided by IV Meloxicam in both soft tissue and hard tissue patients, which would be foreign to the average investor or anyone without a medical degree. Reviewing the clinical data "from the objective perspective of a reasonable investor," the Court is not convinced that the disclosure rendered the misrepresentations not misleading. Fan, 927 F.3d at 716; see also In re Celgene Corp. Sec. Litig., Civil Action No. 18-4772, 2019 WL 6909463, at *17 (D.N.J. Dec. 19, 2019) (finding that defendant's failure to disclose discovery of an effect that would require further safety testing was materially misleading in light of existing disclosure of timeline for submitting NDA).

In summary, Defendants' materiality arguments do not persuade the Court. Assuming the allegations in the Amended Complaint to be true, it is "substantially likely that a reasonable investor would have viewed [the KOLs' opinions] as having significantly altered the 'total mix' of information made available." Matrixx, 563 U.S. at 47 (internal quotation marks and citations omitted). The KOLs raised concerns about IV Meloxicam that could have significantly affected

the likelihood of FDA approval, and because IV Meloxicam is Recro's lead product, investors would have considered the KOLs' feedback highly relevant. Recro's disclosure of the clinical data does not undermine this conclusion, because a reasonable investor cannot be expected to understand complex medical data. Plaintiff has pleaded materiality under Section 10(b).

2. Loss Causation

Defendants argue that Plaintiff has failed to adequately plead loss causation because "Plaintiff does not allege that any fraudulent statement or omission was the cause of the actual loss suffered." (Motion to Dismiss at 30.) Plaintiff responds that the drop in the price of Recro's stock following the May 24, 2018 press release establishes loss causation. (Plaintiff's Opposition at 27.) The Court concludes that because Plaintiff has adequately alleged a causal nexus between the misrepresentative omissions and the stock drop, loss causation has been pleaded.

Under the PSLRA, a securities fraud plaintiff bears "the burden of proving that the act or omission of the defendant … caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). The PSLRA "makes clear Congress' intent to permit private securities fraud actions for recovery where, but only where, plaintiffs adequately allege and prove the traditional elements of causation and loss." Dura, 544 U.S. at 346. The loss causation inquiry is focused on "how directly the subject of the fraudulent statement caused the loss, and whether the resulting loss was a foreseeable outcome of the fraudulent statement." Berckeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 222 (3d Cir. 2006). Establishing loss causation requires that the plaintiff "demonstrate[] that the fraudulent misrepresentation actually caused the loss suffered." Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 173 (3d Cir. 2001).

The briefing on loss causation focuses on the fact that Plaintiff's loss resulted from Recro's

May 24, 2018 press release announcing the CRL denying Recro's NDA for IV Meloxicam.[7] Although Defendants may be correct that this theory would not be enough, paragraph 124 of the Amended Complaint adequately alleges loss causation.

Paragraph 124 of the Amended Complaint alleges that

> Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired [Recro's] securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases …, the true value of Recro securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Recro securities declined sharply upon public disclosure of the facts alleged … to the injury of Plaintiff and Class members.

Thus, prior to May 24, 2018, Recro's stock price was inflated because of the company's omissions and the injury to Plaintiff was realized when the facts that were allegedly fraudulently omitted were made known. Said differently, the market price for Recro's stock reflected the information that was publicly available at the time. Before May 24, 2018, Recro's stock price was artificially high because the market did not know of the concerns that had been raised by the KOLs. If Recro had not omitted the questions raised by the KOLs regarding IV Meloxicam's manufacturing and efficacy, the market price for Recro's securities would have reflected the extent to which these concerns affected the likelihood of FDA approval. On May 24, 2018, Recro announced the FDA's denial of the NDA, and explained that the CRL was concerned that "data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect does not meet the expectations of the FDA." (Am. Compl. ¶ 53.) The stock price dropped upon this disclosure, causing the injury that Plaintiff complains of.

[7] The Court notes that there is an unsupported inferential leap in this theory of loss causation. As Plaintiff acknowledges, the stock drop occurred as a result of the FDA's denial of the NDA—not as a result of Recro's failure to publicly disclose the opinions of the KOLs. See Am. Compl. ¶ 55 ("Recro's share price was decimated as a result [of] the news [that the FDA decided to deny Recro's NDA for IV Meloxicam]."). Said differently, to make the loss causation theory that is briefed work, Plaintiff would need to connect Recro's allegedly misleading omissions to the stock drop. However, analyzing this theory in depth is unnecessary because, as discussed, Plaintiff alleges that the market price incorporated the omissions at the time of purchase.

This is sufficient to establish loss causation at the motion to dismiss stage. The Third Circuit has squarely held that "where the claimed loss involves the purchase of a security at a price that is inflated due to an alleged misrepresentation, there is a sufficient causal nexus between the loss and the alleged misrepresentation to satisfy the loss causation requirement." Semerenko v. Cendant Corp., 223 F.3d 165, 184 (3d Cir. 2000). Paragraph 124 fits within the scope of this holding, because it alleges that Plaintiff purchased Recro's stock at a price that was artificially inflated due to the omissions, and that Plaintiff was injured by the stock price decline when the omitted information was subsequently disclosed. In other words, because Plaintiff alleges that "the price of [Recro's] security was inflated due to [the] fraudulent [omissions]," its burden on loss causation is met. Berckeley, 455 F.3d at 222.

Defendants argue that Plaintiff cannot plead loss causation because "the FDA denied Recro's NDA for IV [M]eloxicam for both soft tissue and hard tissue procedures, which demonstrates that there was no nexus between any opinions from the alleged KOLs about clinical data relating to soft tissue procedures and the FDA's denial of Recro's NDA relating to both soft tissue and hard tissue procedures." (Motion to Dismiss at 30.) However, because the Amended Complaint alleges that the market price for Recro stock was higher than it would have been absent the omission, the FDA's subsequent denial of approval for both uses does not defeat loss causation. The share price reflected the market's assessment of the value of Recro, which reflected the market's estimated likelihood of FDA approval for either use. Accepting all of Plaintiff's allegations as true, the omission increased the market's estimation of the likelihood of FDA approval for soft-tissue uses, and therefore the stock price. If the information had been disclosed, Plaintiff either would not have purchased or would have purchased at a lower price. In either scenario, the omission's effect on the stock price is independent of any effect that the likelihood

of FDA approval for hard tissue procedure uses had on the stock price.

The Amended Complaint adequately pleads loss causation for purposes of Defendants' Rule 12 challenge. However, Plaintiff will bear a heavy burden in proving this element—whether Plaintiff can ultimately establish loss causation is an entirely different question.

3. Scienter

Defendants argue that Plaintiff has not satisfied the PSLRA's "strong inference" standard for scienter allegations. (Motion to Dismiss at 25.) Plaintiff responds that the scienter requirement is satisfied because CW1 had firsthand knowledge of the views of the majority of the KOLs and provided those opinions to Recro and its management. (Plaintiff's Opposition at 24-25.)

The PSLRA requires that a securities fraud complaint plead facts that lead to a "strong inference" of scienter, 15 U.S.C. § 78u-4(b)(2)(A); that is, an intent "to deceive, manipulate, or defraud." Tellabs, 551 U.S. at 313. Scienter may include "either reckless or conscious behavior." Avaya, 564 F.3d at 276 (quoting In re Advanta, 180 F.3d 525, 534-35 (3d Cir. 1999)). "A reckless statement is one involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." Id. at 276 n.42 (quoting Advanta, 180 F.3d at 535).

In Tellabs, the Supreme Court prescribed three rules for assessing scienter on a motion to dismiss. "First, faced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true." Id. at 322. "Second, courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and

matters of which a court may take judicial notice." Id. This includes documents that are "integral to or explicitly replied upon" in the complaint. Burlington, 114 F.3d at 1426 (quoting Shaw v. Dig. Equip. Corp., 82 F.3d 1194, 1220 (1st Cir. 1996) (emphasis omitted)). "Third, in determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences." Id.

The pertinent inquiry is "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Id. at 322-23. In assessing scienter, courts must "consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." Id. at 323-24. To survive dismissal, the inference of scienter "must be cogent and compelling, thus strong in light of other explanations." Id. at 324. A showing of motive and opportunity, though not an independent route to scienter, may be relevant when considered along with the other allegations in the complaint. Avaya, 564 F.3d at 277; see also Frater v. Hemispherx Biopharma, Inc., 966 F. Supp. 2d 335, 349 (E.D. Pa. 2014) (Yohn, J.) ("While allegations relating to motive and opportunity may not independently support a finding of scienter, such considerations may amplify an inference of scienter as part of the holistic information available to the court.").

Plaintiff's allegations of scienter include the following:

- Defendants "knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit," (Am. Compl. ¶ 119);
- "By virtue of their positions at Recro, Defendants had actual knowledge of the materially false and misleading statements … or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants," (Am. Compl. ¶ 121); and
- "[E]ach Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted," (Am. Compl. ¶ 121.)

Plaintiff points to two facts that circumstantially demonstrate Defendants acted consciously or recklessly with respect to the misleading omissions: first, that the information concerning the KOLs' concerns was exposed to Defendants by someone who later became Plaintiff's confidential source (described in the Amended Complaint as "CW1"); and second, that the alleged misstatements involved Recro's lead product. (Plaintiff's Opposition at 25.)

The Court is unpersuaded by Plaintiff's theory that CW1's disclosures to Defendants of the KOLs' concerns are sufficient to establish scienter. The Third Circuit has explained that, where the defendants' purported knowledge comes from the disclosures of a confidential source, applying the PSLRA's particularity standard to the scienter element requires the court to "evaluat[e] the 'detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.'" Avaya, 564 F.3d at 263 (quoting Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 147 (3d Cir. 2004)); see also In re Cigna Corp. Sec. Litig., No. Civ. A. 02-8088, 2006 WL 263631, at *2 (E.D. Pa. Jan. 31, 2006) (Baylson, J.) ("[E]ven if personal sources must be identified in a complaint, there is no requirement that they be explicitly named, provided they are described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged."). The weight that confidential source allegations are given depends on the degree to which they are particularized: if the allegations are inadequate with respect to these criteria, then they may be discounted "steeply," but if they are sufficiently specific, they should not be dismissed simply because they are anonymous. Avaya, 564 F.3d at 263.

Here, Plaintiff's description of CW1 permits the inference that CW1 had an adequate basis for his knowledge. Plaintiff explains that "CW1 was employed at [Recro] as the Regional Medical

Affairs Director from June 2017 through September 2017, and the National Director of Medical Affairs from October 2017 through May 2018. CW1 was a member of Recro's Leadership Team. He led and coordinated medical conferences attended by KOLS … During such conferences, CW1 frequently spoke with Recro's KOLs. CW1 also travelled to KOL facilities where he personally spoke with Recro's KOLs." (Am. Compl. ¶ 39.) Thus, Plaintiff has "adequately described the duration of … [CW1's] employment, the time period during which [CW1] acquired the relevant information, and how [CW1] had access to [the] information." Avaya, 564 F.3d at 263.

However, the allegations related to CW1's communication of that information to Defendants are insufficient to create a "strong inference" that Defendants acted with scienter.

Plaintiff alleges that CW1 reported to Defendant McCallum (Recro's CMO), and that CW1 attended Recro's Leadership Team meetings "every few weeks." (Am. Compl. ¶ 40.) These meetings were attended by, among others, Defendant McCallum and Defendant Harlow. (Am. Compl. ¶ 40). Although Defendant Henwood did not generally attend, she received reports from McCallum and Harlow. (Am. Compl. ¶ 40.) It was presumably at the Leadership Team meetings that CW1 expressed the concerns he and the Medical Affairs Team had about the manufacturing of IV Meloxicam and the efficacy of the drug in soft tissue procedures.[8] Plaintiff alleges that "CW1 … and his Medical Affairs Team reported at meetings to [Recro's] leadership that the KOLs had concerns about … Sharr and his oversight of manufacturing in Ireland … and the lack of robust data concerning IV [M]eloxicam's analgesic efficacy to convince soft tissue surgeons to use IV [M]eloxicam in soft tissue procedures." (Am. Compl. ¶ 42.) Plaintiff notes that "CW1 confirmed

[8] The Amended Complaint states that CW1 brought forth his concerns "at meetings to the Company's leadership." (Am. Compl. ¶ 42.) The Amended Complaint never explicitly states that these meetings were the same Leadership Team meetings described in paragraph 40 of the Amended Complaint. However, based on Plaintiff's representation in the opposition memorandum that CW1 "conveyed [his knowledge of the KOLs' concerns] to Defendants and other top executives at Leadership Team meetings," the Court assumes that the ambiguous "meetings" Plaintiff refers to were the Leadership Team meetings described elsewhere in the Amended Complaint. (Plaintiff's Opposition at 24-25.)

that [the KOLs'] concerns [regarding manufacturing] were provided to Henwood, McCallum, [and] Harlow." (Am. Compl. ¶ 67.)

The paragraphs cited above relating to CW1 do not meet the requirements of a "strong inference" of scienter because they lack many of the key requirements of particularized pleading. For example, Plaintiff merely alleges that these concerns were communicated at "Leadership Team meetings [that occurred] every few weeks"—Plaintiff does not specify when these meetings occurred, where they were held, or how often the concerns were communicated.[9] (Am. Compl. ¶ 40.)

Moreover, the Amended Complaint is deficient in describing what was conveyed to Recro and its management regarding the KOLs' concerns about IV Meloxicam's efficacy in soft tissue procedures.[10] There are two allegations that relate to the information CW1 provided to Defendants regarding the KOLs' efficacy concerns:

- "CW1 stated that he and his Medical Affairs Team reported at meetings to [Recro's] leadership that the KOLs had concerns about … the lack of robust data concerning IV [M]eloxicam's analgesic efficacy to convince soft tissue surgeons to use IV [M]eloxicam in soft tissue procedures," (Am. Compl. ¶ 42); and
- "CW1 … stated that Defendants knew that while 99.9% of KOLs were convinced that IV [M]eloxicam should be used in [hard tissue] procedures, Defendants also knew that KOLs stated that IV [M]eloxicam should not be used in soft tissue procedures because the clinical trial data for the efficacy of IV [M]eloxicam in hard tissue procedures … was far more compelling than the

[9] The lack of information regarding the meetings at which CW1 communicated with the KOLs is important because the statements were made over a roughly one year period starting in July 2017 and ending in May 2018. Depending on when CW1 communicated the KOLs' concerns, the confidential source information may not bear on scienter at all for statements that were made prior to CW1's disclosures.

[10] Paragraphs 61 to 64 of the Amended Complaint lay out, in detail, the concerns that the KOLs brought to CW1 regarding foreign manufacturing. For example, Plaintiff alleges "CW1 stated that approximately 30% of KOLs expressed their concern to CW1 about IV [M]eloxicam being manufactured overseas" that was based, partially, on "their experience with foreign manufacturing of drugs." (Am. Compl. ¶¶ 61, 62.) The KOLs also conveyed to CW1 concerns regarding "Recro's level and quality of oversight of the manufacturing process." (Am. Compl. ¶ 63.) The Amended Complaint then alleges that "CW1 and CW1's Medical Affairs Team reported the KOLs' concerns regarding Sharr and foreign manufacturing of IV [M]eloxicam to Recro's top leadership," (Am. Compl. ¶ 67.) This level of detail is likely sufficient to establish the "what" for purposes of scienter. However, as discussed, the allegations regarding the concerns communicated to Recro about IV Meloxicam's efficacy in soft tissue procedures were far sparser, and because efficacy is the primary theory of omission, scienter is not adequately pleaded.

> clinical trial data for the drug's efficacy in soft tissue procedures," (Am. Compl. ¶ 69.)

These allegations are insufficient to establish exactly what was conveyed by CW1 to Recro and Defendants regarding the substance of the efficacy-related concerns raised by the KOLs. The extent to which the KOLs were concerned about the clinical data is unclear from the Amended Complaint. While Plaintiff alleges that "99.9% of KOLs" were convinced that IV Meloxicam was efficacious in hard tissue procedures, the Amended Complaint is silent on the percentage of Recro's 200–300 KOLs who expressed concerns about soft tissue efficacy. (Am. Compl. ¶ 69.) This is relevant because the more KOLs who raised questions, the more reckless a course of action that seemingly ignores these concerns; conversely, if only a small percentage of KOLs raised concerns, then Recro's representations regarding IV Meloxicam's efficacy may not have been reckless. The Court is unable to evaluate the strength of any competing inferences without understanding the specific substance of the concerns that CW1 conveyed to Recro and its leadership.

Additionally, the Amended Complaint is devoid of allegations that CW1 communicated to Recro that the KOLs' concerns about soft tissue efficacy were correlated with the likelihood of FDA approval. For example, while paragraph 61 of the Amended Complaint directly relates the KOLs' concerns regarding overseas manufacturing of IV Meloxicam to the prospect of receiving FDA approval, see Am. Compl. ¶ 61 ("When CW1 spoke to KOLs about FDA approval 'the thing that kept coming back up over and over again … the thing they were concerned about was a potential packaging issue or manufacturing issue because the manufacturer was in Ireland'"), there is no analogous paragraph relating the KOLs' concerns about soft tissue efficacy to the KOLs' concerns about the likelihood of FDA approval. The fact that an undisclosed number of KOLs expressed concerns about efficacy is not enough to establish that Defendants were "either reckless

or conscious" as to the alleged omissions. Avaya, 564 F.3d at 276.

Finally, Plaintiff's allegations related to "the who" of the scienter analysis are lacking. Plaintiff alleges that CW1 communicated the KOLs' concerns to Defendant Henwood, Defendant McCallum, and Defendant Harlow. Significantly, there is no allegation that either Defendant Celano or Defendant Lake attended the meetings at which CW1 purportedly articulated the KOLs' efficacy concerns. Therefore, since Plaintiff's primary theory of scienter appears to be CW1's disclosures, there is no basis from which to conclude that either Celano or Lake acted consciously or recklessly with respect to the omissions. To the extent that Plaintiff relies on Celano and Lake's status as high level company executives to establish their scienter, that theory is unpersuasive. Although IV Meloxicam was Recro's key product and Celano and Lake held high level positions, Plaintiff suggests no reason why these executives—who served in financial roles—would have been aware of the KOLs' opinions regarding clinical data. See also Egalet, 340 F. Supp. 3d at 512 ("[K]knowledge of [drug's] prospects for FDA approval in general is different from knowledge that [the drug] would or would not receive approval ….").

The two cases cited by Plaintiff to support the theory that the confidential witness information establishes scienter are distinguishable. In Aviva Partners LLC v. Exide Technologies, the plaintiffs successfully established scienter by reference to "information obtained from and corroborated by the confidential informants." Civil Action No. 05-3098 (MLC), 2007 WL 789083, at *18 (D.N.J. Mar. 13, 2007). Because the Aviva plaintiffs alleged thirteen very specific facts that the company "encountered during the class period, which were either brought to the individual defendants' attention or such that persons in their positions would have been aware of them," a strong inference of scienter was pleaded. Id. at *19. As an initial matter, Aviva is distinguishable on the basis of the amount of the defendants' knowledge—there, the plaintiffs had

pleaded very specific "detail[ed]" facts that the individual defendants knew, while here, the allegations are far vaguer. Id. at *18. This case is also unlike Aviva because the only source of Defendants' alleged knowledge of potential inefficacy in IV Meloxicam is CW1's communication of the KOLs' concern. There is no independent corroboration, and the only allegation regarding a red flag is the information conveyed by CW1.

Similarly, in the second case cited by Plaintiff, In re Viropharma Inc. Securities Litigation, the "strong inference of scienter [was] supported by [the] [p]laintiff's several confidential witnesses, and the allegations [were] supported by documentation in the [c]omplaint." 21 F. Supp. 3d 458, 473 (E.D. Pa. 2014) (Jones II, J.) (emphasis added). There were other facts alleged in the complaint that suggested scienter (including contradiction between the defendants' private information and public statements, allegations of stock sales, and facts establishing both motive and opportunity), and the confidential witness information simply provided corroboration. Id. at 473-74. By contrast, here the primary theory of scienter is the information provided by CW1; it is not corroborative of an allegation of independent knowledge.

Recro's disclosure of the clinical data is also relevant to scienter because it undermines Plaintiff's position that Defendants were acting with the intent to defraud investors about the likelihood of IV Meloxicam receiving FDA approval, at least as to the alleged omissions regarding IV Meloxicam's efficacy. Plaintiff alleges that the concerns of Recro's KOLs regarding IV Meloxicam's efficacy in soft tissue procedures came from the clinical data. (Am. Compl. ¶ 69.) However, this very same data was disclosed in Recro's public filings. (Motion to Dismiss at 20.)

The fact that the clinical data was available and could have been analyzed by a set of KOLs or other medical professionals hired by Plaintiff suggests that Recro did not mislead the market about IV Meloxicam's efficacy. The Court is not suggesting that there was an affirmative

obligation on Plaintiff to independently analyze the clinical data. Rather, the fact that Plaintiff, or any other shareholder, could have conducted their own verification process is suggestive of a lack of opportunity and possibly lack of scienter. Cf. Rahman v. Kid Brands, Inc., 736 F.3d 237, 245 (3d Cir. 2013) ("It also is significant that [the plaintiff] did not demonstrate that the individual defendants had a motive for their wrongful conduct … [because the] presence [of motive] can be persuasive when conducting a holistic review of the evidence."). Without a contrary explanation, the Court cannot ignore the inference that the disclosure of the clinical data points to—that Defendants did not have the intent to defraud the market regarding soft tissue efficacy, because if they had, they would not have disclosed the data.

Viewed "holistically," these allegations do not suggest a strong inference of scienter. Tellabs, 551 U.S. at 326. Without further detail as to exactly what CW1 communicated regarding the KOLs' efficacy concerns, and to whom, and when/how often, it is impossible to evaluate the plausibility of competing inferences, such as the possibility that the percentage of KOLs who expressed concerns was insignificant, or that further clinical study would alleviate the concerns, or that reasonable KOLs differed on the efficacy question. Said differently, the Court is unable to conclude that the scienter inference is at least as compelling as any competing inference from the "whole factual picture painted by the [Amended Complaint]." Avaya, 564 F.3d at 269. As a result, Plaintiff has not pleaded scienter with the particularity that is required by the PSLRA.[11]

F. Section 20(a) Claims

Because Plaintiff's Section 20(a) claims depend on the existence of an underlying violation of Section 10(b), and because the Court concludes that Plaintiff has not stated a claim under

[11] The allegations related to individual scienter are insufficient, and even assuming that the Third Circuit accepted the doctrine of corporate scienter, Plaintiff has not alleged facts that fit within the scope of that doctrine. Therefore, the Court will not analyze the scienter of Recro, a corporation.

Section 10(b), it follows that the Section 20(a) claims necessarily fail. See, e.g., City of Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 177 (3d Cir. 2014) ("Because the [plaintiffs] have failed to adequately plead a predicate section 10(b) violation, their section 20(a) claim must be dismissed."). Therefore, Plaintiff's Section 20(a) claims, which are asserted against all five Individual Defendants in Count II, are dismissed without prejudice.

VII. Leave to Amend

Plaintiff requests that the Court grant leave to amend if the Motion to Dismiss is granted. (Plaintiff's Opposition at 28 n.22.) The Court will grant Plaintiff leave to amend to address the deficiencies identified in this Memorandum.

Rule 15 requires that a court "freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Third Circuit has made clear that leave to amend should be refused "only on the grounds of bad faith, undue delay, prejudice, or futility." Alston v. Parker, 363 F.3d 229, 236 (3d Cir. 2004). Granting leave would be futile when "the complaint, as amended, would fail to state a claim upon which relief could be granted." Burlington, 114 F.3d at 1434. The court must apply Rule 12(b)(6)'s standard of legal sufficiency when analyzing futility. Id.

The Amended Complaint does not contain factual allegations that support a "strong inference" of scienter, which is why Defendants' Motion to Dismiss is granted. However, if Plaintiff can supplement the complaint with additional factual allegations related to scienter, it may survive another Rule 12(b)(6) challenge. Therefore, the Court is not convinced that amendment would be futile. Defendants contend that any amendment of the complaint would be futile because it would not "change the contents of Defendants' statements on which Plaintiff has based its claims, that all of the information purportedly omitted by Defendants was already public, or the forward-looking nature of many of the statements …." (ECF 33, Defendants' Reply at 10.)

However, as discussed, the Amended Complaint is dismissed due to the insufficiency of the scienter allegations, and because Plaintiff may be able to adequately replead that element, it is not certain that amendment would be futile. See, e.g., Utesch v. Lannett Co., Inc., 316 F. Supp. 3d 895, 907 (E.D. Pa. 2018) (Beetlestone, J.) ("Plaintiff will be given leave to amend to address the scienter pleading deficiency.").

VIII. Conclusion

Defendants' Motion to Dismiss the Amended Complaint is granted without prejudice because the Amended Complaint does not plead a "strong inference" of scienter as required by the PSLRA. Plaintiff may file a second amended complaint within fourteen days of this Memorandum.

An appropriate order follows.

O:\CIVIL 18\18-2279 ALberici v RecroPharma\18cv2279 Memorandum re Motion to Dismiss.docx

APPENDIX

Statements Alleged to be False And/Or Misleading			
Am. Compl. ¶	**Source of Statement**	**Date**	**Statement**
Statements Issued During Third Quarter of 2017 (July 1, 2017–September 30, 2017)			
74	Investor presentation attached to Form 8-K	July 17, 2017	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** Hospital Outpatient & Ambulatory Surgical Settings ***Target Strategy – GI*** and Orthopedic ***Surgeons*** Hospital Outpatient Facilities Top 426 facilities equal 50% • ***4,100 facilities with targeted GI*** & Ortho (CPTs) ***procedures*** Ambulatory Surgical Centers Top 300 • ***2,000 facilities with targeted GI*** & Ortho ***procedures***
75	Form 10-Q	Aug. 11, 2017	Certification that the Q2 2017 10-Q ***"does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."***
76	Form 10-Q	Aug. 11, 2017	Our Acute Care segment is primarily focused on developing innovative products for commercialization in hospital and other acute care settings. Our lead product candidate, IV meloxicam, has successfully completed two pivotal Phase III clinical trials, a large Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, we enrolled a total of approximately 1,100 patients in our Phase III program. At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing. ***Our Acute Care segment***

			has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, initial pre-commercialization of meloxicam and personnel costs.
77	Investor presentation attached to Form 8-K	Aug. 17, 2017	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]**
78	Investor presentation attached to Form 8-K	Sept. 19, 2017	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]**
Statements Issued During Fourth Quarter of 2017 (October 1, 2017–December 31, 2017)			
80	Press Release	Oct. 10, 2017	MALVERN, Pa., Oct. 10, 2017 (GLOBE NEWSWIRE) -- Recro Pharma, Inc. (Nasdaq:REPH), a revenue generating specialty pharmaceutical company focused on therapeutics for hospital and other acute care settings, today announced an oral presentation highlighting clinical efficacy data from its Phase III study evaluating intravenous (IV) meloxicam 30mg for the treatment of acute postoperative pain in patients following abdominoplasty surgery. The poster was presented at Plastic Surgery The Meeting 2017, hosted by the American Society of Plastic Surgeons (ASPS), taking place October 6-10, 2017, in Orlando, FL. The poster, which was selected as a "Top 6" of the meeting, describes the clinical performance of IV meloxicam 30mg, including achievement of the study's primary endpoint, a statistically significant difference in Summed Pain Intensity Difference (SPID) over the first 24 hours (SPID24) compared to placebo, along with detailed secondary endpoints. "The Phase III results presented this year at Plastic Surgery The Meeting demonstrate the efficacy of IV meloxicam 30mg, including significant reductions in pain, as evidenced by SPID24, meaningful reductions in opioid rescue use and improvements across numerous other pain relief metrics," said

			Stewart McCallum, M.D., F.A.C.S., Chief Medical Officer of Recro Pharma and co-author of the poster. "On the safety front, IV meloxicam 30mg continues to demonstrate a favorable safety and tolerability profile with a low incidence of adverse events (AEs), serious AEs and infusion events. ***We believe these results demonstrate IV meloxicam 30mg's ability to provide rapid and durable pain relief following abdominoplasty surgery and support its potential to be an attractive non-opioid alternative for physicians and patients for the treatment of acute, postoperative pain."***
81	Investor presentation attached to Form 8-K	Oct. 11, 2017	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]** *** ***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care*** ***Core Target Procedures*** Orthopedic (Hip/Knee, Spine other) General Surgery ***GI/Colorectal***
82	Form 10-Q	Nov. 9, 2017	Certification that the Q3 2017 10-Q ***"does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."***
83	Form 10-Q	Nov. 9, 2017	Our Acute Care Segment is primarily focused on developing innovative products for commercialization in hospital and other acute care settings. Our lead product candidate, IV meloxicam, has successfully completed two pivotal Phase III clinical trials, a large Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, we enrolled a total of approximately 1,100 patients in our Phase III program. At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has accepted the NDA for review and set a PDUFA date of May 26, 2018. ***Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, initial pre-commercialization of meloxicam and personnel costs.***
84	Investor presentation attached to	Nov. 14, 2017	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in:

	Form 8-K		Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]** ******* ***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care*** ***Core Target Procedures*** Orthopedic (Hip/Knee, Spine other) General Surgery ***GI/Colorectal***
85	Investor presentation attached to Form 8-K	Nov. 28, 2017	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]** *** ***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care*** ***Core Target Procedures*** Orthopedic (Hip/Knee, Spine other) General Surgery ***GI/Colorectal***
Statements Issued During First Quarter of 2018 (January 1, 2018–March 31, 2018)			
87	Investor presentation attached to Form 8-K	Jan. 8, 2018	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]**

			*** ***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care*** ***Core Target Procedures*** Orthopedic (Hip/Knee, Spine other) General Surgery ***GI/Colorectal***
88	Investor presentation attached to Form 8-K	Feb. 7, 2018	***IV Meloxicam Target Opportunity*** ***Intra-abdominal Procedures*** • Surgeons have keen interest in: Avoidance of opioids Avoidance of troughs in existing non-opioid pain med options • ***If approved, could answer needs through:*** ***Relief of moderate to severe pain over 24 hours*** ***Reducing LOS*** **[length of stay]** *** ***Targeted Accounts Cover ~12.6M Patients Across All Settings Of Care*** ***Core Target Procedures*** Orthopedic (Hip/Knee, Spine other) General Surgery ***GI/Colorectal***
89	Investor presentation attached to Form 8-K	Feb. 7, 2018	Statement in regard to "***Defining Our Market***" that there is a "***Large Addressable Patient Opportunity" of "29 Million Patients***" ***for "addressable procedures where [the] greatest IV meloxicam use is anticipated."*** It is anticipated that ***"17%"*** of these 29 million patients will have ***"core procedures"*** by ***"gastrointestinal/colorectal surgeons"*** involving the ***"belly [and] bowel".***
90	Investor presentation attached to Form 8-K	Feb. 7, 2018	Statement in sections titled "What We Have Learned: Market Research Feedback on Clinical Profile" and "IV Meloxicam Receptivity: Anticipated Usage" that ***"In multiple market research surveys, the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases."*** The presentation also stated that ***"core target procedures"*** include ***"GI/Colorectal"***.
91	Form 10-K	Mar. 2, 2018	Certification that the 2017 10-K ***"does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."***
92	Form 10-K	Mar. 2, 2018	Manufacturing and Supply of our Acute Care Product Candidates ***We currently rely on contract manufacturers to produce drug product for our clinical studies under cGMPs [Current Good Manufacturing Practice regulations enforced by the FDA], with oversight by***

			our internal managers. We plan to continue to rely on contract manufacturers to manufacture development quantities of our product candidates, as well as commercial quantities of our product candidates, if and when approved for marketing by the FDA. We currently rely on a single manufacturer for the clinical supplies of our drug product for each of our product candidates and do not currently have agreements in place for redundant supply or a second source for any of our product candidates ….
93	Form 10-K	Mar. 2, 2018	Our Acute Care segment is primarily focused on developing innovative products for commercialization in hospital and other acute care settings. Our lead product candidate, IV meloxicam, has successfully completed three Phase III clinical trials, two pivotal efficacy trials, large double-blind Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, the total NDA program included over 1,400 patients. At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has accepted the NDA for review and set a PDUFA date of May 26, 2018. ***Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, pre-commercialization of meloxicam and personnel costs.***
94	Investor presentation attached to Form 8-K	Mar. 9, 2018	Statement in regard to "***Defining Our Market***" that there is a "***Large Addressable Patient Opportunity"*** of ***"29 Million Patients***" for ***"addressable procedures where [the] greatest IV meloxicam use is anticipated."*** It is anticipated that ***"17%"*** of these 29 million patients will have ***"core procedures"*** by ***"gastrointestinal/colorectal surgeons"*** involving the ***"belly [and] bowel"***. The presentation also stated that ***"core target procedures"*** include ***"GI/Colorectal".***
95	Investor presentation attached to Form 8-K	Mar. 9, 2018	Statement with respect to "IV Meloxicam Receptivity: Anticipated Usage" that ***"In multiple market research surveys, the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases."***
Statements During Second Quarter of 2018 (April 1, 2018–June 30, 2018)			
97	Form 10-Q	May 9, 2018	Certification that the Q1 2018 10-Q ***"does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."***
98	Form 10-Q	May 9, 2018	Our Acute Care segment is primarily focused on developing and commercializing innovative products for hospital and related acute care settings. Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed three Phase III clinical trials for the management of moderate to severe pain, consisting of two pivotal efficacy trials and a large double-blind Phase III safety trial, as well as other safety studies. Overall, the total new drug application, or NDA, program included over 1,400 patients. In late July 2017, we submitted a NDA to the U.S. Food and Drug Administration, or FDA, for IV meloxicam 30mg for the

			management of moderate to severe pain. The FDA has accepted the NDA for review and set a date for decision on the NDA under the Prescription Drug User Fee Act, or PDUFA, of May 26, 2018. ***Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, pre-commercialization of meloxicam and personnel costs.***
99	Statement during earnings call	May 9, 2018	Given the increasing urgency of the national opioid crisis, we believe IV meloxicam has to potential to serve as a valuable analgesic alternative for healthcare institutions, physicians and patients. ***We believe, we've identified clear addressable segments of the market, that will benefit from IV meloxicam's profile. Segments in which we believe, IV meloxicam's profile provides both clinical and economic value.*** From a clinical standpoint, we believe IV meloxicam can effectively treat pain, while reducing opioid consumption, which reduced opioid related adverse events. From an economic standpoint, we believe IV meloxicam's durable 24-hour dosing profile will allow ambulatory surgical centers to perform more complex procedures with same date discharge, while managing pain. And hospitals to accelerate patients discharge and reduce length of stay through reduction of opioids. ***A pillar of our strategy is identifying the key surgeons specifically*** orthopedic surgeons, general surgeons and ***GI colorectal surgeons***. ***The procedures conducted by these surgeons represent a primary opportunity both in ambulatory surgical centers and in hospitals.***
100	Investor presentation attached to Form 8-K	May 10, 2018	Statement in regard to "***Defining Our Market***" that there is a "***Large Addressable Patient Opportunity"*** of ***"29 Million Patients***" for ***"addressable procedures where [the] greatest IV meloxicam use is anticipated."*** It is anticipated that ***"17%"*** of these 29 million patients will have ***"core procedures"*** by ***"gastrointestinal/colorectal surgeons"*** involving the ***"belly [and] bowel"***. The presentation also stated that ***"core target procedures"*** include ***"GI/Colorectal"***.
101	Investor presentation attached to Form 8-K	May 10, 2018	Statement with respect to "IV Meloxicam Receptivity: Anticipated Usage" that ***"In multiple market research surveys, the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases."***